Exhibit 11

K113618

MAR 19 2012

Section 5 – 510(k) Summary for ClearCorrect System

1. Submission Sponsor

ClearCorrect LLC
15151 Sommermeyer St.
Houston, Texas 77041
United States
Phone: (713) 850-1036 x 11
e-mail: pgarcia@clearcorrect.com
Contact: Pedro Garcia, VP of QA/RA ClearCorrect LLC

2. Submission Correspondent

Emergo Group
611 West 5th Street, Third Floor
Austin, TX 78701
Cell Phone:
Office Phone: (512) 327.9997
Fax: (512) 327.9998
Contact: Cheryl Fisher, Sr. QA/RA Consultant
Email: project.management@emergogroup.com

3. Date Prepared

10/31/2011

4. Device Name

Trade/Proprietary Name: ClearCorrect System
Common/Usual Name: Invisible braces
Classification Name: Sequential Aligner
Classification Regulation: 872.5470
Classification Panel: 872 Dental
Product Code: NXC
Device Class:2

FDA Establishment Registration #: 3007130440-

5. Predicate Devices

ClearCorrect System, ClearCorrect LLC K082556
FS Aligner System, Sybron Dental Specialties K093821

6. Device Description

The ClearCorrect device is fabricated of clear thin thermoformed polyeurathane plastic in a sequential series to progressively reposition the teeth. Corrective force to straighten the teeth is delivered via minor changes into a position in each subsequent aligner.

7. Intended Use

The ClearCorrect System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The ClearCorrect System positions teeth by way of continuous gentle force.

8. Summary of Usage

A dental health care professional (e.g. orthodontists or dentists), prescribes the ClearCorrect system based on an assessment of the patient's teeth, determines a course of treatment with the system, takes molds of the patient's teeth and completes a prescription form. The molds and prescription are sent to ClearCorrect. Utilizing standard dental software used for tooth alignment, ClearCorrect designs a series of plastic trays intended to gradually realign the patient's teeth in accordance with the physician's prescription. The prescribing physician reviews and approves the model scheme before the molds are produced. Once approved, ClearCorrect produces the trays, which are formed of clear, thin thermoformed polyeurathaneplastic. The trays are sent back to the dental health care professional, who then provides them to the patient, confirming fit and design. Over a period of months, additional trays are provided sequentially to the patient by the dental health care professional to gradually move the target teeth to the desired position. The dental care professional monitors treatment from the moment the first aligner is delivered to when treatment is completed. The trays are held in place by pressure and can be removed by the patient at any time. This technology is essentially identical to that used by a number of sequential alignment systems, including the predicates referenced below.

9. Technological Characteristics and Substantial Equivalence

The following table compares the ClearCorrect Systemsto the predicate devices, ClearCorrect System unmodified and the FS Aligner System with respect to intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Comparison Table

Feature	FS	ClearCorrect	ClearCorrect modified	Comparison
510 (k) Number	K093821	K082556	Not yet assigned	
Manufacturer	Sybron Dental Specialties	ClearCorrect LLC	ClearCorrect LLC	
Classification #	872-5470	872-5470	872-5470	Same
Product Code	NXC	NXC	NXC	Same
Intended Use	The FS Aligner System	The	The	Comparable in

	is intended for minor anterior tooth movement in patients with permanent dentition (second molars). The FS Aligner System positions teeth by way of continuous gentle force.	ClearCorrectSystem is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars), The ClearCorrect System positions teeth by way of continuous gentle force	ClearCorrectSystem is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars), The ClearCorrect System positions teeth by way of continuous gentle force	the FS Aligner and the same in the unmodified ClearCorrect System
Mode of Action	Each appliance is worn by patient as determined by dental practitioner. Generally 2-4 weeks prior to using the next sequential aligner	Alignment of teeth by sequential use of preformed plastic trays	Alignment of teeth by sequential use of preformed plastic trays	Comparable in the FS Aligner System and the same in the unmodified ClearCorrect System
Material	Thin thermoformed plastic material	Thermoformed polycarbonate	Thermoformed polyeurathane	Comparable over all three systems
OTC or Rx	Rx	Rx	Rx	Same

10. Non-Clinical Testing

1. Visual Performance
2. Mechanical Performance
3. Device Processing performance
4. Biocompatibility

Materials

- USP Class VI

Finished Product Biocompatibility

- ISO 10993-5 Cytotoxicity
- ISO 10993-10 Intracutaneus Intradermal reactivity, Oral Mucosa Irritation test, Maximum test for Delayed Type Hypersensitivity

11. Clinical Testing

There was no clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. The substantial equivalence of the device is supported by the

non-clinical testing. The verification and validation testing of the device biocompatibility and performance testing was found to be acceptable and supports the claims of substantial equivalence.

12. Conclusion

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device.

It has been shown in this 510(k) submission that the difference between the ClearCorrect System and the predicate devices do not raise any questions regarding its safety and effectiveness. The ClearCorrect System, as designed and manufactured, is determined to be substantially equivalent to the referencedpredicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

ClearCorrect LLC
C/O Ms. Cheryl Fisher
Senior QA/RA Consultant
Emergo Group
611 W. 5TH Street, Third Floor
Austin, TX 78701

MAR 19 2012

Re: K113618
Trade/Device Name: ClearCorrect System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: NXC
Dated: March 1, 2012
Received: March 2, 2012

Dear Ms. Fisher:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K113618

Indications for Use Statement

510(k) Number (if known): Not Assigned K113618

Device Name: ClearCorrect System

Indications for Use:

The ClearCorrect System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The ClearCorrect System positions teeth by way of continuous gentle force.

Prescription Use X (Part 21 CFR 801 Subpart D)
AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K113618